REMARKS

Claims 1-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hayden (U.S. Patent No. 3,249,502); claims 14-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Geistlich et al. (GB Patent No. 905195); claims 1-5, 7, 9-13 and 19-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McKnight et al. (Ulster Med. J. 1968) in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery System) and Braun et al. (Pharmaceutical Formulation); claims 6 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Coles et al., Ansel and Braun et al., and Clark and in further view of Flick (Cosmetic and Toiletry Formulations, 2nd ed.).

The rejections of claims 1-18 are moot in view of the present amendment where claims 1-18 have been canceled without prejudice.

With respect to the originally filed method claims, claims 1-5, 7, 9-13 and 19-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McKnight et al. (Ulster Med. J. 1968) in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery System) and Braun et al. (Pharmaceutical Formulation); claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. and further in view of Peterson et al. (U.S. Patent No. 5,861,144); and claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. and Peterson et al. and further in view of Flick.

Claim 19 recites a method of treating a wart including the step of providing a pharmaceutical preparation that includes formaldehyde as an active ingredient and further includes at least one other ingredient. In complete contrast to prior art preparations, the wart remover preparation of the present invention is in the form of a powder or a gel. As mentioned in the present specification, a common treatment for warts is the application of an acid or other composition to the surface of the wart by effectively "painting" the medication onto the wart surface due to the liquid nature of the medication. These types of products are commercially distributed in stores and

typically come with an applicator, as part of the bottle cap, that includes a brush that is soaked in the medication and then the captured medication is applied to the wart. However and as noted in the specification, there are a number of disadvantages associated with using a liquid medication. For example, the liquid typically runs over the surface and thus causes a messy situation in addition to causing the medication to be displaced from the target area where the medication should lie for proper treatment of the wart.

In rejecting independent method claim 19, the Examiner has combined a number of references and in particular, the Examiner contends that the McKnight et al. reference teaches treating warts by soaking the wart in 5% formalin on a regular basis. The Examiner contends that Ansel teaches the use of topical gels as a carrier for drugs and the Braun reference teaches a formulation and method for making a clear topical gel.

Applicant respectfully traverses this rejection for the following reasons. While McKnight realizes that a benefit is obtained by bathing a wart in a formalin solution, the reference only limits itself to a discussion of administering a liquid formalin solution and then soaking the wart with the formalin solution. There is absolutely no suggestion or even contemplation in the McKnight reference of administering the formalin in a state different than a liquid soak. The Ansel reference only generically discusses the use of topical gels as a carrier for drugs; however, this reference is completely silent and clearly does not disclose or suggest the application of a gel or a powder composition (as opposed to a liquid) to the surface of a wart for treatment thereof. In other words, Applicant respectfully submits that the present invention offers an advancement in the area of wart treatment by realizing that improved results are obtained if the vehicle or carrier for delivering the medication is not in the form of a liquid composition but rather is in a solid form, such as a gel or powder. This type of product is more easily applied and importantly, the gel or powder has an improved tendency to stay situated at the target location compared to liquid compositions which merely run off the target site (i.e., the wart).

Applicant disagrees with the Examiner's contention that it would have been obvious for one of skill in the art to merely modify the formalin liquid solution in McKnight et al. by making it

into a gel form. Neither of these references recognizes that in the treatment of warts, a solid composition (gel or powder) provides advantageous results and an improved way of treating warts. The Ansel reference fails to recognize or even contemplate the inclusion of formaldehyde in a gel composition, while the McKnight et al. reference only discusses the treatment of warts in terms of applying a liquid to the skin. Since neither of these references nor any of the other references, including the Hayden reference, contemplate preparing a gel or powder composition and then applying the gel to a wart, the rejection of claim 19 is improper and should be withdrawn.

In other words, previous handling and treatment of warts with formaldehyde was carried out by dispensing a liquid solution of formalin over the area so as to bath the wart. This is much different than providing the active formaldehyde ingredient as a solid (gel or powder) and applying it to the skin in this state. Since the present method of treating a wart is neither disclosed nor suggested or contemplated by the cited references, the present rejection must be withdrawn. None of the other references cures this deficiency since the other references, such as the Hayden reference, are not directed to treatment of warts but instead, at best, only disclose the inclusion of formaldehyde in substances that are used in completely unrelated fields, such as embalming procedures, etc. As such, these references fail to provide the necessary teaching of applying a gel or powder to a wart for treatment thereof as opposed to the conventional treatment technique of applying a liquid.

The references that the Examiner refers to as disclosing medications in powder form once again suffer from the same deficiencies of the other cited references in that they fail to show a powder having formaldehyde in the claimed amount as well as other ingredients that make the preparation suitable for application to a wart for treatment thereof. Once again, none of the cited references, alone or in combination, disclose or even suggest providing a dry powder having the claimed composition and then applying it to the wart. Applicant submits that the previous treatment protocol for warts involved an application of a liquid solution or the application of a medicated patch; however, the use of a powder based product (or a gel) that includes formaldehyde in the proper amount and form has not been envisioned or contemplated. Based on the foregoing, the current rejection is improper.

Reconsideration and allowance of claim 19 are earnestly solicited.

Claims 20-23 should be allowed as depending from what should be an allowed independent claim 19.

Claim 24 has been rewritten to state a method of treating a surgical site which includes the positive step of removing excessive moisture at the site by applying the claimed preparation. For the same or similar reasons discussed above, Applicant respectfully requests withdrawal of the rejection of claim 24. Once again, formaldehyde in this form and amount has not previously been applied as part of a surgical procedure either prior to or after another procedure is performed to treat a skin growth, e.g., a laser procedure to treat the growth.

Reconsideration and allowance of claim 24 are earnestly solicited.

Claims 25-27 should be allowed as depending from what should be an allowed independent claim 24.

New claims 28 and 29 have been added and consideration and favorable treatment of these claims are respectfully requested. Claim 28 recites a method of treating a wart including the step of forming a gel preparation that includes formaldehyde as an active ingredient and at least one non-active ingredient that causes the preparation to be in the form of a gel. The formaldehyde is present in an amount greater than or equal to about 10% by weight. The gel preparation is applied to a surface of the wart to cause drying of the wart.

For the reasons discussed above the method of claim 28 is neither disclosed nor suggested by the cited references. Claim 28 recites the step of forming a gel preparation that includes formaldehyde as an active ingredient and at least one non-active ingredient that causes the preparation to be in the form of a gel. The formaldehyde is present in an amount greater than or equal to about 10% by weight.

Consideration and allowance of claim 28 are respectfully requested in view of the above comments with respect to amended claim 1.

For the reasons discussed above the method of claim 29 is neither disclosed nor suggested by the cited references. Claim 29 recites the step of forming a rehydratable powder that includes formaldehyde as an active ingredient and silica to cause the preparation to be in power form. The formaldehyde is present in an amount greater than or equal to about 10% by weight and the silica is present in an amount of 45% or greater by weight.

Consideration and allowance of claim 29 are respectfully requested in view of the above comments with respect to amended claim 1.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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